Message

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Risk Policy Report - 05/20/2014

EPA Nominee Declines Vitter's Call For Second Formaldehyde Risk Review

Posted: May 19, 2014

Thomas Burke, President Obama's nominee to serve as EPA's research chief, is, for now, declining a request from Sen. David Vitter (R-LA) to send EPA's next draft risk assessment of formaldehyde to the National Academy of Sciences (NAS) for peer review, saying such a commitment is premature.

"While I can assure there will be rigorous peer review of the revised formaldehyde document, I believe it is premature for me to provide assurance that another NAS committee be convened specifically to re-review formaldehyde." Burke told Vitter in a recently obtained written response to questions following his confirmation hearing late last year. *Relevant documents are available on InsideEPA.com. (Doc. ID: 2471295)*

Vitter's spokesman did not respond to a request for comment. Vitter's question signals a renewed effort by the lawmaker to seek an NAS review of any revised formaldehyde assessment EPA may develop.

It was Vitter, in 2009, who forced EPA to seek NAS review of an earlier formaldehyde assessment by blocking confirmation for Paul Anastas, Burke's predecessor.

Vitter insisted that the agency seek NAS review of its draft assessment that proposed that exposure to the substance could cause certain forms of leukemia, and calculated a risk estimate based on that ednpoint. But the resulting NAS review, published in 2011, provided a scathing critique of the agency's draft assessment as well as its broader Integrated Risk Information System (IRIS) program, prompting a series of reforms and an overhaul of the formaldehyde assessment.

"The NAS report on formaldehyde was critical of the process as well as the underlying science that EPA used in its draft assessment," according to Vitter's questions for Burke which were obtained through a Freedom of Information Act request.

"Given the significance of this risk assessment to the scientific process and for restoring the public confidence in EPA's science, it is imperative that you commit to having the NAS [relook] at the next iteration of the formaldehyde IRIS assessment. Can I have your assurance that this peer review will take place?" Vitter asked.

But Burke said he was not willing at that time to commit to such a review, though he did not rule it out in the future. "If confirmed, I will work to implement the recommendations of the NAS Formaldehyde Committee, not only for formaldehyde, but for all IRIS documents."

As a result of Senate rule changes, Vitter no longer has the power to block executive branch nominees though Burke and several other EPA nominees are still awaiting confirmation.

While the NAS recently released a new report favorably reviewing the progress EPA has made in reforming the IRIS program, Vitter remains critical of the program and EPA science in general.

"Overall, the changes that EPA has proposed shows some initial improvements in their chemical assessment process, but by no means is this report a reason to spike the football," Vitter said in a May 6 statement on NAS' review of the IRIS program.

"Chemical safety is a top priority, and we need to ensure that the EPA's basic goals are to develop assessments that provide an evidence-based foundation for ensuring that chemical hazards are assessed and managed well. If the EPA actually implements the National Academies suggestions, the process will slowly move to becoming much more effective and credible but this is just a first step and they have a long way to go."

While Vitter offered EPA faint praise in his response to the new NAS report, his questions for Burke suggest a series of fixes he would like to see the agency make to the IRIS program, as well as other EPA risk assessment practices -- though in several cases the nominee appears to reject the GOP senator's questions.

For example, Vitter echoes industry calls for EPA to "reality check" formaldehyde and other risk assessments to ensure they do not result in regulatory levels that fall below naturally occurring levels of the substances that are also produced industrially.

But Burke says EPA should continue to assess substances' hazards regardless of exposure levels and then consider how to deal with naturally occuring levels during the risk management phase.

Should IRIS assessments pass a reality check and "accommodate levels associated with existing natural exposures that are not known to be associated with any adverse effects at these low exposure levels," Vitter asks.

But Burke responded that "The adverse effects of hazardous agents are not driven by whether or not they are 'naturally' occurring."

He added that "[n]atural occurrence and background levels are more appropriately considered in the risk management strategy."

Vitter also presses Burke regarding the idea of reality checking IRIS assessments using empirical data. "EPA's use of assumptions that it claims are 'public health protective' which err on the side of overstating risk when data are lacking ... What are your views on the use of empirical data as a 'reality check' on overly conservative risk assessments, particularly those resulting from modeled or extrapolated data?"

Burke replied that "I believe that the fundamental mission of EPA is to protect public health, and therefore agree with approaches that are 'public health protective.' I also believe that the fundamental challenge in assessing risks is a lack of data. Therefore, it is not really valid to say that the EPA assumptions 'overstate the risks when data are lacking.' ... In the absence of data, safety factors provide a time tested public health strategy to safeguard communities. I agree that more specific evidenced based approaches to safety factors and the protection of vulnerable subpopulations are needed. Also, risk characterization should include presentation of multiple modeling approaches to assist decision making and provide a 'reality check' based on empirical data."

Burke appears more willing to consider Vitter's call to ensure independent assessments of IRIS reviews. For example, Vitter asks Burke to "commit to ensuring that a 3rd party, independent of the IRIS Program, is tasked with ensuring that EPA staff have sufficiently considered and responded to peer reviewer and public input before assessments and other documents are finalized?"

Burke responded that "responding to peer review and public comments is an important step in completing a scientific product. It is my understanding that responses to public comments are documented in an appendix to each IRIS assessment so that interested parties can judge the adequacy of the response. If confirmed, I look forward to working with scientists in the agency to explore this issue further."

Vitter's more than 50 questions to Burke also address other issues that are relevant to the formaldehyde assessment, such as his question about how Burke, a trained epidemiologist, views the best balance of epidemiology and toxicology data in risk assessment.

"How do you view the intersection between epidemiology and toxicology?" Vitter asks Burke. "Many critics believe EPA has been overly reliant on epidemiology and deemphasized mechanistic research that provides guidance for dose-response calculations."

Multiple industry sources have voiced this concern about formaldehyde, arguing that animal toxicology studies show no evidence of formaldehyde exposure causing leuekmias, and there is no mechanistic explanation for how formaldehyde exposure could cause systemic disease. By contrast, formaldehyde exposure is more broadly agreed to cause nasal cancers. EPA and other agencies, such as the National Toxicology Program and the International Agency for Research on Cancer, classified formaldehyde as a leukemogen based largely on a 2010 epidemiological study of a score of Chinese workers exposed to formaldehyde on the job. Industry representatives have raised numerous concerns about the study's findings, and argue that it should not trump toxicological and mechanistic data that do not show leukemia risks.

"Toxicology and epidemiology are both essential if we are to understand and manage risks. Both types of studies have advantages and limitations, and the best approach is to improve how we consider the full body of evidence from both of these disciplines. While well conducted studies of human populations are considered the "gold standard" for assessing human health risks, toxicology provides important information when human studies are lacking or not possible," Burke replied to Vitter's question. "The large majority of IRIS risk assessments are based upon animal toxicology, including assessments of cancer risk, because the dose response data from most human studies is very limited. I do not believe there is a bias against toxicology studies. If confirmed, I will work with risk assessors and other scientists to provide clear criteria for consideration of epidemiology and toxicology in the risk characterization process. I will also support continued research to improve the application of mechanistic data to risk assessment." -- *Maria Hegstad*